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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/932,494 | 08/17/2001 | Trang T. Le | C-3320/1/US | 5208 |

7590 09/27/2002

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| EXAMINER |
|---|
| TRAN, SUSAN T |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Applicati n No. | Applicant(s) | |
|---|---|---|---|
| | 09/932,494 | LE ET AL. | |
| | Examiner | Art Unit | |
| | Susan Tran | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

Receipt is acknowledged of applicant's Declaration and Extension of Time filed 01/17/02, and Information Disclosure Statement filed 07/02/02.

### *Information Disclosure Statement*

The information disclosure statement filed 07/02/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-11, 26-29, 33-35, 39-42, 54-68, 77-83, 86-89 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15, and 17-32, 34, and 36-39 of copending

Application No. 09/932,500 ('500). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claims a process for preparing an oral fast-melt tablet formulation comprising wet granulating a selective cyclooxygenase-2 (COX-2) inhibitor together with binding agent; blending with the drug a saccharide having low moldability; blending the granules with at least one of a lubricant, a sweetening agent and a flavoring agent; and compressing the resulting blend into tablet. The process is found in claim 1. The lubricant, sweetening and flavoring agent are found in claims 39. The saccharide with low moldability is found in claims 10, 11, 33-35, and 64-68. therefore, those of ordinary skill would expect a similar fast-melt tablet comprising COX-2 inhibitor from the use of the claimed invention given the claims of '500. There are no unusual and/or unexpected results, which would be rebut prima facie obviousness. As such, the instant claims would have been obvious given the claims of '500, which set out a similar process for preparing an oral fast-melt tablet formulation using the same steps, machinery, and conditions as claimed herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

In examining this application, it is noted that several co-pending applications appear to be directed towards the same subject matter. Particularly, 09/731,350, 09/874,504, 09/932,537, 09/932,500, and 10/113,157; all appear to direct to process for preparing fast-melt tablet formulation of COX-2 inhibitor, and their use for the same treatment. Applicant is requested to forward a copy of the claims of each application in order to resolve possible double patenting issues.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 10-16, 18-21, 23-44, 46-49, 51-56, and 60-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, and Nakao et al. US 6,277,878.

Mizumoto teaches quick-dissolved compressed tablet comprising saccharide having high moldability and saccharide having low moldability (columns 6-7), drug, and additive agents (columns 13-19, claims 1-6). The drug used is in an amount of about 50%, and is not limited but include both analgesic and anti-inflammatory drugs (column 7). The method for preparing the tablet is disclosed in columns 12-13. The composition further comprising lubricant, *e.g.*, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, or talc (column 13, lines 52-55). The hardness, strength, and disintegration time is disclosed in column 11.

Mizumoto does not specifically teach the claimed active agent to be a COX-2 inhibitor. However, COX-2 inhibitor is a well-known analgesic agent, particularly, anti-inflammatory, and can be used in conjunction with other analgesic agents.

Nakao teaches COX-2 inhibitors, which can be used in combination with varieties of analgesic agents, *e.g.*, codeine (columns 22-23). Thus it would have been *prima facie* obvious for one of ordinary skill in the art to prepare the quick-dissolved

formulation of Mizumoto using the COX-2 inhibitor in view of the teaching of Nakao, because the references teach the advantageous result in the use of anti-inflammatory drug.

The examiner notes that the cited references are silent as to the amounts of glidant, and wetting agent being incorporated in the formulation. However, it is the position of the examiner that no criticality is seen in the particular amounts since the prior art in using the claimed ingredients, obtains the same results desired by the applicant, *e.g.*, tablet comprising analgesic agent having disintegration rate of 1-40 seconds. See also *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Claims 7-9, and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Nakao et al., in view of Talley et al. US 5,633,272 and Talley et al. US 5,760,068.

Mizumoto and Nakao are relied upon for the reason stated above. The references are silent as to the specific COX-2 derivatives.

Talley '272 teaches COX-2 such as valdecoxib is a known anti-inflammatory agent.

Talley '068 teaches COX-2 such as celecoxib is a known anti-inflammatory agent.

Thus, it would have been obvious for the skilled artisan to, by routine experimentation modify the anti-inflammatory agent of Mizumoto and Nakao using the

valdecoxib and celecoxib in view of the teachings of Talley, because the references teach the advantageous results in the use of the well-known anti-inflammatory agents.

Claims 17, 22, 45, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. and Nakao et al., in view of Jain et al. US 6,316,029.

Mizumoto and Nakao are relied upon for the reason stated above. The references do not teach the specific glidant, and wetting agent.

Jain teaches process for preparing rapidly disintegrating solid oral dosage form comprising sodium lauryl sulfate and silicon dioxide (columns 8-9). Thus, it would have been *prima facie* obvious for one of ordinary skill in the art to use the sodium lauryl sulfate and silicon dioxide in view of the teaching of Jain to prepare the quick-dissolved formulation of Mizumoto since sodium lauryl sulfate and silicon dioxide are well known tabletting aids. The expected result would be compressed tablet having good hardness and dissolved quickly upon contact with fluid.

***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ducharme et al. and Gao et al. are cited as being of interest for the teaching of COX-2 inhibitor formulation.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600